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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/079,040 | 02/20/2002 | Peter L. Ryan | RU-0176 | 6411 |

7590 05/20/2003
Licata & Tyrrell P.C.
66 E. Main Street
Marlton, NJ 08053

EXAMINER

DAVIS, DEBORAH A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1641

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DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/079,040

Applicant(s)

RYAN ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 recites the limitation "the level" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al (Breed Differences in circulating Equine Relaxin, Biology of Reproduction, 1992, Vol. 46, pages 648-652).

Stewart et al anticipates claims 1-2 by teaching a method for measuring levels of relaxin in plasma of a pregnant mare before and after the administration of a drug or treatment (see abstract and introduction) wherein a homologous equine relaxin Radio Immunoassay (RIA) has been developed and used to measure plasma relaxin activity in thoroughbred mares during gestation until the time of foaling. Burros and Thoroughbred mares stimulated to deliver with oxytocin (treatment) showed an elevation in relaxin levels wherein the sensitivity to oxytocin (treatment) appears to develop late in

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gestation, as mares induced to abort in midpregnancy did not show a rise in relaxin (page 651, column 2, paragraph 2). Animals that exhibited adverse pregnancy outcomes had depressed relaxin concentrations at some point during gestation prior to the loss (page 651, column 2, paragraph 2). With respect to claim 2, the preamble recites a diagnostic kit, but will not be given patentable weight because the content of the kit is not clear and the language is considered to be intended use. Therefore, the instant reference reads on a diagnostic kit wherein it teaches detecting relaxin levels in a radioimmunoassay.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Ryan et al (Relaxin 2000, Proceedings of the International Conference on Relaxin & Related Peptides 22-27, October 2000, Broome, Australia).

Ryan et al clearly anticipates the instant claims in teaching a method for predicting treatment efficacy in pregnant mares affected by a disease or condition that alters placental function and results in a problematic pregnancy or delivery (page 91, see paragraphs 1-3). Relaxin levels were measured in the plasma of pregnant mare before administration of a drug (page 95, paragraphs 1-3). Relaxin levels in the plasma

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of mares increased following drug treatment (page 96, paragraphs 1-3 and page 97 paragraph 1). With respect to claims 2, the preamble recites a diagnostic kit, but will not be given patentable weight because the content of the kit is not clear and the language is considered to be intended use. Therefore, the instant reference reads on a diagnostic kit wherein it teaches detecting relaxin levels in an homologous equine relaxin RIA (page 94, paragraph 1).

Conclusion

7. No claims are allowed.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Cross et al discloses clinical signs and solutions of equine fescue toxicosis (Equine Fescue Toxicosis: Signs and Solutions, J. Animal Science, 1995, Vol 73, pages 899-908).

B. Stewart et al discloses the development of a homologous equine relaxin assay (Development of a Homologous Equine Relaxin Radioimmunoassay, Endocrinology, 1986, Vol 119, No. 3, Pages 1100-1104).

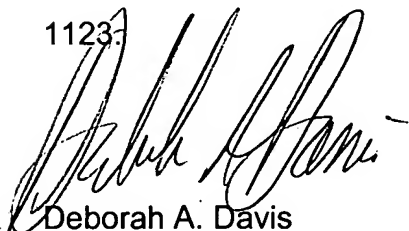
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123:



Deborah A. Davis
CM1, 7D16
May 16, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

05/19/03